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In re Application of	:
SZPIRER ET AL.	:Decision on Petition
Serial No.: 10/507,923	:
Filed : July 19, 2005	:
Attorney Docket No.: VANM290.001APC	:

This letter is in response to the Petition under 37 C.F.R. 1.144 filed on June 10, 2008 requesting review of a lack of unity determination. The delay in acting upon this petition is regretted.

BACKGROUND

This application was filed as a national stage application under 35 USC 371 of PCT/BE03/00045 and as such, is eligible for unity of invention practice.

In a written lack of unity determination mailed March 29, 2007, the examiner divided claims 15-33 into three groups and then requested that applicants select particular species depending on which group was selected. The examiner provided a prior art reference to support this determination for lack of unity.

On September 24, 2007, applicants elected Group I without traverse, claims 15-24, 26-28, and "does not comprise a selectable marker," "wherein the genetic sequence encoding the antidote is not added to the construct," "ccdB," "yeast cell," "an exogenous compound," "chloroplast," and "two different toxic genes" all with traverse.

In the first Office action of the merits mailed December 12, 2007, the examiner considered the traversal and made the unity of invention determination FINAL. Claims 15, 16, 18, 22-24, 26-27, 35 were examined. Claims 15-16, 18, 22-24, 26-27, 35 were rejected under 35 USC 101, 35 USC 112/1st paragraph written description, 35 USC 112/1st paragraph enablement, 35 USC 112/2nd paragraph, 35 USC 102(a), 35 USC 102(e) and 35 USC 103(a).

A response to the Office action was filed on June 10, 2008 which included amendments to the claims, a response and this petition requesting reconsideration under 37 C.F.R 1.144 of the lack of unity requirement.

DISCUSSION

Applicants' petition filed June 10, 2008 and the file history have been considered carefully.

The petition argues that the unity of invention determination was incorrect because there is a special technical feature which is a contribution over the art.

As provided in the PCT International search and preliminary examination guidelines, paragraph 10.03 provides that Lack of unity of invention may be directly evident "*a priori*," that is, before considering the claims in relation to any prior art, or may only become apparent "*a posteriori*," that is, after taking the prior art into consideration. For example, independent claims to A + X, A + Y, X + Y can be said to lack unity *a priori* as there is no subject matter common to all claims. In the case of independent claims to A + X and A + Y, unity of invention is present *a priori* as A is common to both claims. However, if it can be established that A is known, there is lack of unity *a posteriori*, since A (be it a single feature or a group of features) is not a technical feature that defines a contribution over the prior art.

Moreover, the PCT International Search and Preliminary Examination Guidelines, published January 2004 provide Example 38 that addresses unity of invention with regard to a method of screening. The claims of Example 38 are reproduced below.

Example 38: Method of Screening and Compounds Identified by the Method

Claim 1: A method to identify compounds that are antagonists of receptor R comprising the steps of contacting cells expressing on their outer membrane receptor R with its natural ligand; observing the binding of the ligand; contacting said cells bound to said ligand with a candidate compound selected from a library of compounds; and observing any change in the binding of the ligand.

Claim 2: Compound X, having formula 1.

Claim 3: Compound Y, having formula 2.

Claim 4: Compound Z, having formula 3.

Example 38 states that "No manufacturing relationship exists between the screening method and the claims compounds. Further a screening method is not a method of using claims compounds X, Y and Z."

In contrast to ISPE Guidelines Example 38, in the instant application, only method claims are presented; in the instant application, no claims are directed to any products. Determination of unity of invention among method claims generally involves analysis of the active steps required by the methods. In the instant application, the methods of Group I and II do not share a special

technical feature with elected Group III for the following reasons. Group III requires the active step of inducing maturation of the immature macrophage or immature dendritic cell whereas Groups I and II do not require any active step of induction. Screening methods, such as Groups I and II are commonly used to both identify compounds with the desired activity, as well as identify compounds which lack the desired activity. Groups I and II in fact are directed to determining whether there is any specific binding to the DDR1. This active step is not required in Group III. For Groups I and II when the screening method is preformed using a candidate compound that is not a DDR1 agent, no induction occurs. Moreover, Group III requires the active step of activating DDR1, which is not required for Groups I or II. As supported by the analysis in Example 38, a method of screening for a product is not a method of using or using the product.

Thus, there is no special technical feature to link Groups (I and II) with Group III.

Group V, Claims 26-30, requires the active step of administering an agent that specifically binds to DDR1b. This technical feature is not required by any of the other groups.

Group VII, Claims 48-50, requires the special technical feature of contacting a leukocyte with an antibody that specifically binds to DDR1a which is not required by any of the other groups.

For these reasons, Groups I, II, V and VII lack unity of invention with elected Group III.

Turing now to the consideration of unity of invention between Groups III and VI, representative claims from each group are set forth below:

Claim 11, from elected Group III

> 11. (Previously presented) A method of inducing maturation of an immature macrophage or an immature dendritic cell that expresses Discoidin Domain Receptor 1 (DDR1), comprising:
>
> contacting the immature macrophage or the immature dendritic cell with an effective amount of a DDR1-activating agent, thereby inducing maturation of the immature macrophage or the immature dendritic cell that expresses DDR1.

Claim 31 from non-elected Group VI

> 31. (Withdrawn) A method of activating a neutrophil or a lymphocyte, comprising
>
> activating a Discoidin Domain Receptor 1 (DDR1) signalling pathway in the neutrophil or the lymphocyte, thereby activating the neutrophil or the lymphocyte.

A comparison of Claims 11 and 31 shows that Group VI does not share a same or corresponding technical feature with elected Group III. Group VI, Claims 31-33 and 46-47, are drawn to activating a DDR1 pathway in the neutrophil or lymphocyte, thereby activating the neturophil or lymphocyte. This technical feature is not required by Group III. Claim 31 is a method of activating a neturophil or a lymphocyte (B or T cells); this technical feature is not required by Group VI. Thus, Group III and Group VI lack unity of invention, a priori.

Turning now to the consideration of unity of invention between Groups III and IV, representative Claim 23, from non-elected Group IV is set forth below:

> 23. (Withdrawn) A method for producing an antigen presenting macrophage or dendritic cell, comprising
>
> contacting an immature monocyte or an immature dendritic cell with an agent that activates Discoidin Domain Receptor 1 (DDR1) in the presence of an antigen,
>
> thereby producing an antigen presenting mature dendritic cell or an antigen presenting macrophage.

Claim 11 of Group III and Claim 23 of Group IV require contacting the immature macrophage or immature dendritic cell with an effective amount of a DDR1 activating agent to induce maturation of the immature macrophage or the immature dendritic cell that expresses DDR1 or to produce an antigen presenting mature dendritic cell or antigen presenting macrophage. While claims 11 and 23 are worded differently, the technical features required the claims are similar. The specification discloses that "activation of DDR1 by a DDR1-activating agent induces the maturation of a dendritic cell precursor, for example, a monocyte into a macrophage or a dendritic cell. Contacting a dendritic cell precursor with an effective amount of an antigen, in addition to an effective amount of a DDR1-activatign agent, can induce the maturation of the dendritic cell precursor into an antigen –presenting dendritic cell." (pages 2-3, bridging paragraph.) For these reasons, Group IV, Claims 23-25, have unity of invention with elected invention of Group III, Claims 11-22 and newly added Claims 55-57.

Further more, 37 CFR 1.475(b) provides guidance concerning various categories of invention permitted for national stage filings under 35 USC 371.

> 1.475 Unity of invention before the International Searching Authority, the International Preliminary Examining Authority and during the national stage
>
> (b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:
>
> (1) A product and a process specially adapted for the manufacture of said product; or
>
> (2) A product and process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
(4) A process and an apparatus or means specifically designed for carrying out the said process; or
(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

In this case, the method of screening for an agent and a method of using the agent do not appear to be within any of the combinations of categories listed above, thus a lack of unity of invention is permitted.

DECISION

Accordingly, the petition filed under 37 CFR 1.144 is **GRANTED-IN-PART**.

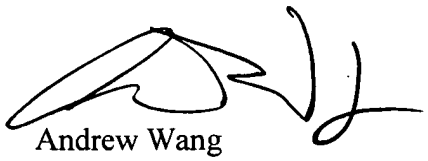
The restriction requirement is maintained between elected Group III and non-elected Groups I, II, V, VI and VII.

The restriction requirement is withdrawn between elected Group III and Group IV. Group IV (Claims 23-25) have been rejoined with previously examined Group III (Claims 11-22 and newly added Claims 55-57).

The application will be forwarded to the examiner to consider the papers filed 10 June 2008 and to prepare an Office action addressing the claims of Groups III and IV consistent with this petition decision.

Any request for reconsideration must be filed within two (2) months of the mailing date of this decision.

Should there be any questions regarding this decision, please contact Special Program Examiner Julie Burke, by mail addressed to Director, Technology Center 1600, PO BOX 1450, ALEXANDRIA, VA 22313-1450, or by telephone at (571) 272-1600 or by Official Fax at 703-272-8300.



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